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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,546	03/20/2001	Karl Kolter	51284	9100

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EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/811,546

Applicant(s)

KOLTER ET AL.

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 January 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-19 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-19 and 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt of request for extension of time (granted) and amendment both filed 1-8-03 is acknowledged. Claims 1, 6, 7-8, 18, and 21 have been amended and claims 22-24 have been added as requested. Claims 1, 3-19, and 21-24 are pending.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1 and 3-19, 21-24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kolter et al (DE 197 09 663; hereafter '663 –US 6,066,334 is relied upon as an English translation).**

3. '663 discloses delayed release dosage forms having polyvinylpyrrolidone and polyvinylacetate polymer mixtures. The instant water soluble and lipophilic polymers and water-soluble swelling polymers are also disclosed and ingredients (abstract; C 2, L 23-C 5, L 5; examples; claims).

### ***Response to Arguments***

4. Applicant's arguments filed 1-8-03 have been fully considered but they are not persuasive. Applicant argues that '663 discloses rapid release formulations and can not therefore anticipate the instant claims since they are directed toward delayed release. However, "delayed release" is a subjective term and the instant claims do not set forth

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any parameters defining the fashion in which the formulation provides delayed release. Moreover, '663 provides release occurs up to an hour later (i.e. complete release of drug is delayed over an hour). Accordingly, '663 meets the claims. Applicant also argues that '663 discloses that the content is restricted to 0.5 to 20% while the instant claimed invention is preferably from 20 to 60%. However, no such limitation is in the claims.

**5. Claims 1, 4-5, 8-12, and 15-19, 21-22, and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ortega (4,837,032; hereafter '032).**

6. '032 discloses delayed release dosage forms having polyvinylpyrrolidone and polyvinylacetate polymer mixtures with water-soluble polymers (abstract; C 2, L 15-42; C 3, L 1-68; examples). The amounts of ingredients are within the instant claimed ranges.

#### ***Response to Arguments***

7. Applicant's arguments filed 1-8-03 have been fully considered but they are not persuasive. Applicant argues that '032 does not disclose a formulated mixture of PVP and polyvinyl acetate (PVA). This argument is not persuasive/understood. Example 1, for example, discloses a mixture of cellulose acetate phthalate and theophylline granules mixed with PVP and PVA.

#### ***Claim Rejections - 35 USC § 103***

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8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**10. Claims 1 and 3-19, 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kolter et al (DE 197 09 663; hereafter '663 –US 6,066,334 is relied upon as an English translation).**

11. '663 teaches delayed release dosage forms having polyvinylpyrrolidone and polyvinylacetate polymer mixtures. The instant water soluble and lipophilic polymers and water-soluble swelling polymers are also disclosed and ingredients (abstract; C 2, L 23-C 5, L 5; examples; claims. Manipulation of amounts of ingredients would have been obvious to one skilled in the art at the time of the invention with the motivation of adjusting the retardant/disintegration effects of the composition.

***Response to Arguments***

12. Applicant's arguments filed 1-8-03 have been fully considered but they are not persuasive. Applicant argues that '663 teaches rapid release formulations and can not therefore render the instant claims obvious since they are directed toward delayed release. However, "delayed release" is a subjective term and the instant claims do not set forth any parameters defining the fashion in which the formulation provides delayed release. Moreover, '663 provides release occurs up to an hour later (i.e. complete release of drug is delayed over an hour). Accordingly, '663 meets the claims. Applicant also argues that '663 teaches that the content is restricted to 0.5 to 20% while the instant claimed invention is preferably from 20 to 60% and that the instant invention has a hardness different than '663. However, no such limitations are in the claims.

**13. Claims 1, 4-5, 8-12, and 15-19, 21-22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ortega (4,837,032; hereafter '032).**

14. '032 teaches delayed release dosage forms having polyvinylpyrrolidone and polyvinylacetate polymer mixtures with water-soluble polymers (abstract; C 2, L 15-42; C 3, L 1-68; examples). The amounts of ingredients are within the instant claimed ranges. Manipulation of amounts of ingredients would have been obvious to one skilled in the art at the time of the invention with the motivation of adjusting the binding effects of the composition.

***Response to Arguments***

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15. Applicant's arguments filed 1-8-03 have been fully considered but they are not persuasive. Applicant argues that '032 does not teach a formulated mixture of PVP and polyvinyl acetate (PVA) having a hardness as in the instant invention. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., hardness) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Double Patenting***

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1, 3-19 and 21-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,066,334. Although the conflicting claims are not identical, they are not patentably distinct from each other because while '334 recites rapid release, this is a

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subjective term and it also requires that release occurs up to an hour later. This is interpreted as delayed release. No other characteristics appear to differentiate the claims.

### ***Response to Arguments***

18. Applicant's arguments filed 1-8-03 have been fully considered but they are not persuasive. The Obviousness Double Patenting rejection is maintained on the basis that the instant claims do not differentiate delayed release from the release profile set forth in '334 which provides delayed release of the active over an hour. No limitations regarding the content as being between 20 to 60% are in the claims.

### ***Conclusion***

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw  
March 23, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600